

DETAILED ACTION

Response to Amendment

Specification

The amendments to the specification filed on 3/10/2008 have been acknowledged and accepted.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 8, 13, 16, 19, 21, and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Moorhead (6,478,783). Moorhead discloses an implantable access port comprising a housing (18) comprising a fluid chamber in fluid communication with an access aperture and a septum (20) covering the access aperture, a port stem (32) extending from the housing, including a channel (76) in fluid communication with the fluid chamber and a catheter retention feature (distal 80), and a visual indicator marking (proximal 80) disposed on the port stem distal of an outer edge of the housing and proximal of the catheter retention feature, the visual indicator marking distinct from the catheter retention feature, wherein the marking is positioned on the port stem a sufficient distance from the housing outer edge to prevent a catheter proximal end aligned with the marking and compressed by a locking sleeve to keep from abutting the

housing outer edge (the locking sleeve is only functionally claimed). It is the examiner's position that Moorehead discloses the method steps recited by the applicant.

Claims 1-8, 13, 16, 19, 2, and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Watson (5,137,529). Watson discloses an implantable access port comprising a housing (12) comprising a fluid chamber in fluid communication with an access aperture and a septum (20) covering the access aperture, a port stem (62) extending from the housing, including a channel (64) in fluid communication with the fluid chamber and a catheter retention feature (distal protrusion, not numbered), and a visual indicator marking (72) disposed on the port stem distal of an outer edge of the housing and proximal of the catheter retention feature, the visual indicator marking distinct from the catheter retention feature, wherein the marking is positioned on the port stem a sufficient distance from the housing outer edge to prevent a catheter proximal end aligned with the marking and compressed by a locking sleeve to keep from abutting the housing outer edge (the locking sleeve is only functionally claimed), and wherein the marking comprises contrast material (column 7, lines 27-30). It is the examiner's position that Watson discloses the method steps recited by the applicant.

Claims 1, 8, 13, 16, 19, 21-22, and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Whipple (4,963,133). Whipple discloses an implantable access port (10) comprising a housing (16) comprising a fluid chamber in fluid communication with an access aperture and a septum (16b) covering the access aperture, a port stem (14) extending from the housing, including a channel in fluid communication with the fluid chamber and a catheter retention feature (22), and a visual indicator marking (26)

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disposed on the port stem distal of an outer edge of the housing and proximal of the catheter retention feature, the visual indicator marking distinct from the catheter retention feature, wherein the marking is positioned on the port stem a sufficient distance from the housing outer edge to prevent a catheter proximal end aligned with the marking and compressed by a locking sleeve (18) to keep from abutting the housing outer edge. It is the examiner's position that Whipple discloses the method steps recited by the applicant.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 2-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Whipple (4,963,133). Whipple meets the claimed limitations as described above in

reference to claim 1 but fails to include that the marking comprise an ink contrast agent, a ribbon, a metallic ribbon or a shrink-wrap plastic.

Applicant has not disclosed that these specific components solve a stated problem or are for any particular purpose. The instant specification does state that in general the marking does facilitate visualization for proper attachment of a catheter to the port stem. However, the specification does not indicate that these particular components as a marking are needed to the exclusion of other or similar forms of port stem markings. There is no disclosure that the claimed forms of markings are needed to perform this function and that the other form of markings would not perform equally well.

Therefore it appears that the port stem marker as described by Whipple or any form of port stem marker would perform equally well. Accordingly, the use of these forms on markings on the port stem is deemed to be an obvious design consideration, which fails to patentably distinguish over the prior art of Whipple.

Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Moorehead (6,478,783) or Watson et al. (5,137,529) in view of Wiita et al. (4,772,270). Moorehead and Watson disclose all of the limitations recited in claim 21, but fail to teach to include the act of placing a locking sleeve over the port stem and catheter. Wiita discloses an implantable pump system in which a locking sleeve (130) is placed over the catheter and port stem to secure the attachment between the catheter and port stem. Therefore, it would have been obvious to one of ordinary skill in the art at the time

of the invention to modify the devices and methods of Moorehead or Watson with the locking sleeve of Wiita to secure the attachment between the catheter and port stem.

Response to Arguments

Applicant's arguments filed 3/10/2008 have been fully considered but they are not persuasive. In response to the applicant's argument that Moorehead and Watson do not disclose visual indicator markings proximal of the one or more catheter retention features, the examiner respectfully disagrees. The examiner maintains that the structures identified in both references are capable of serving as visual indicator markings.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to THEODORE J. STIGELL whose telephone number is (571)272-8759. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Theodore J Stigell/
Examiner, Art Unit 3763

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763